



JuanB Perez/DC/USEPA/US

11/13/2006 08:35 AM

To NCIC HPV@EPA

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Subject Fw: IUCLID dossier on 1646-75-9

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----- Forwarded by JuanB Perez/DC/USEPA/US on 11/13/2006 08:34 AM -----



"Rusch, George"

&lt;george.rusch@honeywell.com&gt;

11/10/2006 10:11 AM

To NCIC OPPT@EPA, Rtk Chem@EPA

cc

"Jones, John(Specialty Chem)" &lt;jw.jones@honeywell.com&gt;

"Bowmer, C.T. (Tim)" &lt;tim.bowmer@tno.nl&gt;

Subject IUCLID dossier on 1646-75-9

Dear Dr. Townsend

I have finally completed the responses to the comments sent to me by Oscar Hernandez on March 30, 2006.

The revised IUCLID dossier on 2-methyl(2-(methylthio)propionaldehyde oxime (CAS# 1646-75-9). The changes were made in the document using the track change mode wherever possible. In one or two places they had to be included in a different color only. The modifications were made to the draft submitted to the Agency on January 18, 2006.

1. The reference for the vapor pressure has been updated.
2. The partition coefficient was recalculated using EPIWIN 3.12 and the correct value of 0.75 was added to the document.
3. The source for most of the physical properties was verified and the reliability has been changed from (4) to (2).
4. A report with a measured value for water solubility was located and this value added to the dossier. It (27 g/L) is in good agreement with the calculated value (25g/L).
5. The robust summaries for the environmental toxicity studies have been expanded. The studies were conducted in accordance with GLPs.
6. The robust summaries for the repeat dose toxicity and developmental toxicity studies have been expanded.
7. As I indicated in my January 18, 2006 letter, Honeywell did conduct a reproduction study to complete this important area of the dossier. However, we do not feel that a study of chromosomal aberrations is justified for the following reasons:
  - a. The product is only sold to one customer for use at one site
  - b. The product is an intermediate in pesticide production, therefore it is consumed in a reaction in a closed system.
  - c. Two Ames assays and one mouse lymphoma assay have been conducted with this material. It was negative in the two Ames assays and only showed a marginal response at a highly cytotoxic dose in the mouse lymphoma study.
  - d. As a consequence of its limited market and Honeywell's controls on exposure, there is no chronic exposure. As noted in section 1.10 exposure measurements have shown that exposures are below 1 ppm.
8. The data on developmental toxicity were added as requested.
9. The Henry's Law value has been corrected.
10. The report on the Union Carbide acute inhalation of saturated vapor toxicity study can not be located. Therefore a reliability code of 3 "invalid" has been assigned to this study for "data not available for review."

11. Purity of the samples used for the genetic toxicity could not be determined from the article. The study was contracted by NCI and it was stated that their contractor, Illinois Institute of Technology Research Institute, Chicago, IL, acquired the samples. Details of solvent and positive controls were added. As Honeywell is the only producer of this material and our specification is >99% pure, one could assume that the sample was >99% pure. However, I did not change the IUCLID dossier.
12. The robust summaries for fish, invertebrates and algae have been expanded to include more details.

I hope our explanations, modifications and additions have satisfactorily addressed EPAs questions.

Sincerely,  
George M. Rusch  
Director of Toxicology and Risk Assessment  
Honeywell International



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